

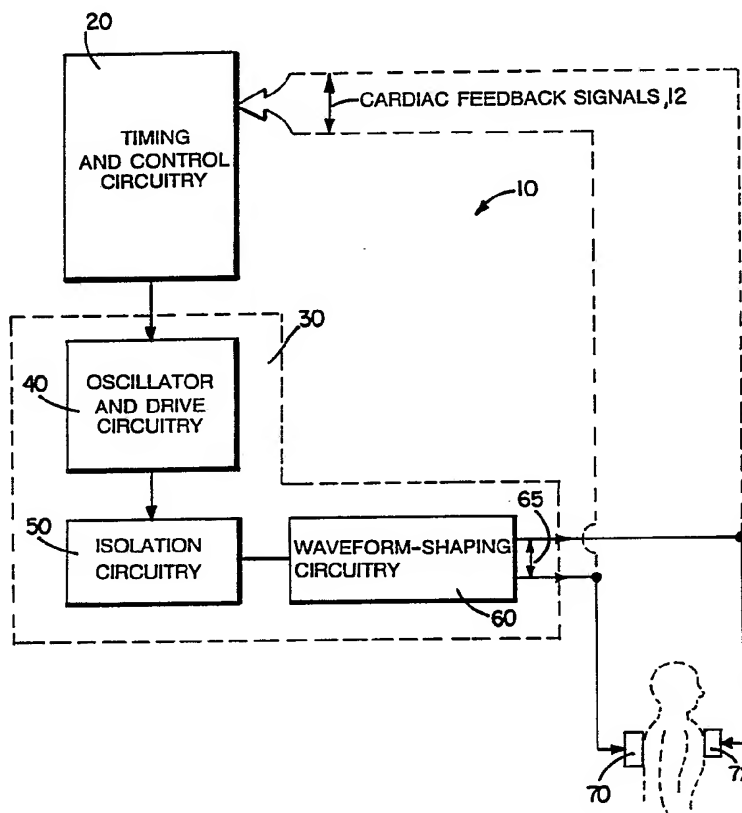


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(54) Title: METHOD AND APPARATUS FOR TRANSCUTANEOUS CARDIAC PACING**(57) Abstract**

Method and apparatus for transcutaneously pacing the heart with background stimuli occurring in the intervals between pacing stimuli to reduce patient discomfort during pacing. The apparatus including a timing and control circuit (20) and a stimuli generating circuit (30) connected to electrodes (70, 72).



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METHOD AND APPARATUS FOR TRANSCUTANEOUS CARDIAC PACINGBackground of the Invention

5 This invention relates to electrically pacing the heart transcutaneously.

During transcutaneous, or external, electrical pacing of a patient's heart, electrical stimuli travel from the pacing apparatus' electrodes to the heart through the patient's skin and skeletal thorax muscles to stimulate the heart. Depending on the magnitude of the stimuli and the characteristics of a particular patient's skeletal muscles, the skeletal muscles may contract in response to the passage of the electrical stimuli through them. Similarly, the passage of the electrical pacing stimuli through the patient's skin may stimulate cutaneous nerves and muscles located near to the skin. This nerve stimulation and skeletal muscle contraction may feel uncomfortable to the patient, or even become painful enough to result in the patient's intolerance of extended transcutaneous heart pacing.

It has been shown (U.S. Patent No. 4,349,030) that the skeletal muscle contractions and cutaneous nerve stimulation associated with conventional transcutaneous heart pacing may be reduced by lengthening the duration of electrical pacing stimuli to greater than five milliseconds.

Summary of the Invention

30 In general, the invention features providing background stimuli in the intervals between pacing stimuli to reduce discomfort during pacing. In preferred embodiments, the background stimuli occur only in the intervals between the pacing stimuli; the background stimuli comprise pulses; the average amplitude of the background pulses is less than the

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average amplitude of the pacing stimuli; the average amplitude of the background pulses is less than 20 mA (more preferably less than 10 mA); and the duty cycle of the background pulses is less than 80% (more preferably less than 50%).

Other features and advantages of the invention will be apparent from the following description of a preferred embodiment and from the claims.

Description of the Preferred Embodiment

Fig. 1 is a block diagram of a pacing stimuli signal generator according to one embodiment of the invention.

Fig. 2 is an illustrative example of electrical stimuli produced by the signal generator of Fig. 1.

Figs. 3A and 3B are illustrative examples of electrical pacing stimuli produced by the signal generator of Fig. 1.

Fig. 4 are plotted characteristics, one for cardiac muscle and one for skeletal muscle and cutaneous nerves, relating a stimulating pulse's strength with the pulse's duration.

Fig. 5 is an example of an electrode configuration for applying the electrical stimuli of Fig. 2 to a patient.

Referring to Fig. 1, there is shown a signal generator 10 for generating electrical pacing stimuli 65 which are to be applied transcutaneously to a patient's heart. The signal generator's timing and control circuitry 20 can accept cardiac feedback signals 12 from the patient to initiate electrical pacing stimuli, or it can operate without such feedback (asynchronous pacing). The timing and control circuitry also sets the timing characteristics of the pacing stimuli, as discussed below. The timing and control circuitry 20 initiates the pacing stimuli by signaling the stimuli generating circuitry 30, which includes

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oscillator and drive circuitry 40, isolation circuitry 50, and waveform-shaping circuitry 60. Oscillator and drive circuitry 40 generates a stream of pulses that are processed by isolation circuitry 50, which isolates the signal generator's internal voltages from the patient, thereby providing electrical hazard protection for the patient during the patient's exposure to the pacing stimuli 65.

Waveform-shaping circuitry 60 receives the isolation circuitry's pulse stream output and modifies signal characteristics of the pulse stream, e.g., pulse shape, polarity, and amplitude, to generate pacing stimuli 65 having user-specified signal parameters. At the signal generator's output, the pacing stimuli 65 are coupled to posterior and anterior electrodes 70, 72, which together externally deliver the electrical stimuli to the patient for transcutaneous pacing of the patient's heart.

Referring to Fig. 2, the signal generator's electrical pacing stimuli output 65 is composed of pacing stimuli 80 and background pulse trains 90. The pacing stimuli 80, comprising, for example, pacing pulse trains, are delivered to the patient to stimulate the patient's heart. The background pulse trains 90 are delivered to the patient in the intervals between the pacing pulse trains, when the heart is not being stimulated. Together, these pulse train stimuli provide effective transcutaneous stimulation of the heart with reduced patient discomfort.

Referring to Fig. 3A, the pacing pulse trains 80 each consist of a series of pulses, with each pulse having a time duration, or width, W_p , which may be different than the duration of the other pulses in the series.

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Referring also to Fig. 4, there are shown characteristic curves for pulse stimuli, representing the relationship between a pulse's current amplitude, or strength, i , and a pulse's duration, t , for stimulating cardiac muscle and skeletal muscle. The duration, T_t , of each pacing pulse train 80 (Fig. 3) is chosen by considering these strength-duration curves. Each curve delineates the minimum duration, t , which an electrical pulse stimulus having a given current amplitude, i , will require to stimulate a muscle. Stated another way, given a pulse amplitude, i , a muscle will not be stimulated unless the pulse duration, t , is on, or to the right of, the corresponding curve. Two different stimulus points lying on the strength-duration curve for a muscle, like points A and B on the cardiac muscle curve, will equally effectively stimulate that muscle.

A minimum pulse amplitude, or rheobase (Ri_c for cardiac muscle and Ri_s for skeletal muscle), defines the smallest pulse amplitude that will stimulate a muscle. Any stimulus having a current amplitude less than the rheobase will not stimulate a muscle, even if the pulse's duration is greater than the rheobase duration, called the utilization time, (Rt_c for cardiac muscle and Rt_s for skeletal muscle). Comparing the strength-duration curves of Fig. 4, the cardiac muscle's utilization time, Rt_c , which is greater than approximately 40 msec, is longer than that of skeletal muscle, having a utilization time Rt_s which is considerably less than 40 msec.

Given these utilization times for cardiac and skeletal muscle, a preferable range for the pacing pulse trains' durations T_t is selected with the following consideration. While any stimulus point on the cardiac strength-duration curve produces effective cardiac stimulation, stimulus points

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having lower current amplitudes tend to produce lower skeletal muscle stimulation than stimulus points having higher current amplitudes, for a given stimulus duration. Accordingly, a pulse stimulus having the characteristics of point A (close to the cardiac utilization time Rt_c) stimulates skeletal muscle less than a pulse stimulus having the characteristics of point B, but will stimulate the heart equally effectively. Therefore, by choosing a pulse train duration around the same duration as the cardiac utilization time, the heart can be adequately stimulated by the pulse train while producing less skeletal muscle stimulation than would be produced by a pulse train of shorter duration and correspondingly higher pulse current amplitudes. The total time duration, T_t , of each pacing pulse train is therefore preferably at least 5 msec, or more preferably 20 msec, but may be of any duration sufficient to stimulate the heart. The maximum preferable pacing pulse train duration is limited to approximately 150 msec because of safety considerations for inducing cardiac fibrillation.

The pulse width W_p and pulse period T_p of each of the pulses in the pacing pulse trains are also selected based on a comparison of the strength-duration relationships for cardiac muscle and skeletal muscle (Fig. 4). As shown in Fig. 4, a minimum pulse duration, called the chronaxie (Ct_c for cardiac muscle and Ct_s for skeletal muscle), is the pulse duration corresponding to a stimulating pulse amplitude equal to twice the rheobase of a muscle. With a pulse stimulus having a duration shorter than the chronaxie, it becomes increasingly difficult to stimulate a corresponding muscle.

Considering the strength-duration curves of Fig. 4, the cardiac muscle's chronaxie Ct_c is approximately equal to 2 msec and the skeletal

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muscle's chronaxie Ct_s is approximately equal to 0.5 msec. A pulse stimulus of a duration shorter than the skeletal muscle chronaxie Ct_s , having, e.g., the duration of a pulse at point C, would therefore tend not to stimulate either cardiac muscle or skeletal muscle. However, a train of such pulses having suitably adjusted amplitudes and a pulse train duration T_t which is longer than the cardiac muscle chronaxie Ct_c , e.g., the stimulus duration of point A, effectively stimulates the heart as if the pulse trains had been filtered by, e.g., the skeletal muscles, to produce a continuous pacing pulse.

Referring again to Fig. 3, based on this consideration, the pulse width W_p of each of the pacing pulses is selected to be less, preferably much less, than the skeletal muscle chronaxie Ct_s (0.5 msec). With pulses of such width, the skeletal muscles tend to be stimulated less than they would if the pacing pulse were a single continuous pulse, but the heart is stimulated as effectively as a continuous pulse. The pacing pulse width W_p for achieving this condition is preferably less than 100 microseconds, and most preferably less than 15 microseconds. Pulse widths of less than about 7 microseconds may produce a pacing pulse frequency which is high enough to cause tissue damage, and thus may need to be avoided. Given the selected pulse width W_p , the pacing pulse period T_p is selected to ensure adequate pacing stimulation, or capture, of the heart. The preferred pacing pulse duty cycle is 66%, but a lower duty cycle, e.g., 20%, or a variable duty cycle may be used, provided the given duty cycle is adequate to capture the heart. Generally speaking, the higher the duty cycle, the higher will be the effective filtered amplitude of the continuous pulse that influences the cardiac muscle.

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A variation in the form of the pacing stimuli is shown in Fig. 3B. The amplitude, i_i , of the first pulse in each pacing pulse train has a subthreshold amplitude, i.e., the amplitude is below the minimum pulse amplitude required for stimulation if the pulse amplitude of a given pulse train remained constant for the duration of the pulse train. Each of the pulses following the initial pulse has an amplitude greater than that of the previous pulses, with some number of trailing pulses all having a maximum current amplitude, i_M . The value of this maximum current amplitude i_M is selected, along with other pulse train characteristics, e.g., pulse train duration, to ensure capture of the heart. For example, a pulse train with a given number of pulses having a maximum current amplitude i_M may require a shorter duration to capture the heart than a pulse train with fewer pulses having a maximum current amplitude that is greater than i_M .

The use of initial, subthreshold pulses, followed by a series of pulses each having an amplitude that is greater than the amplitudes of the preceding pulses is intended to induce accommodation of the skeletal muscles to the pacing pulse train stimuli. Accommodation of a muscle is a physiological phenomenon which can be induced by gradually, rather than abruptly, exposing a muscle to a stimulus amplitude, whereby the stimulating threshold of the muscle is increased beyond the magnitude of the applied stimulus. An accommodated muscle or nerve requires a higher than normal stimulus magnitude to be effectively stimulated, and may even reject stimulation altogether for any magnitude of stimulus increase.

Given the physiological differences between cardiac muscle and skeletal muscle, the amplitudes

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of the pulses in the pacing pulse train are selected to cause accommodation of skeletal muscles but not to cause accommodation of cardiac muscle. By simultaneously achieving these conditions, the pacing pulse trains effectively stimulate the heart but tend to decrease the skeletal muscle stimulation typically associated with the transcutaneous cardiac muscle stimulation.

Referring again to Fig. 2, the background pulse trains 90 are provided during the intervals between the pacing stimuli. Each background pulse train comprises a series of pulses, with the amplitudes of the pulses alternating between a positive amplitude, i_B , and a negative amplitude, $-i_B$, in a biphasic fashion. While Fig. 2 shows each of the background pulses having the same amplitude magnitude, each of the pulses may have differing amplitudes. The magnitude of the alternating amplitudes, $|i_B|$, is preferably below the minimum current amplitude which a pulse, having the width W_B , would require to stimulate the skeletal muscles.

During the interval between each background pulse, the background pulse train has an amplitude, e.g., zero amplitude, that is below the current amplitude required to stimulate skeletal muscle. Given a particularly chosen amplitude between pulses, the pulse width W_B and period T_B of the background pulses are chosen to fulfill two criteria: 1. The duty cycle ($100 \times 2W_B/T_B$) of the background pulses is preferably less than 80%, or more preferably less than 50%, for providing a low average current; and 2. For a given i_B , T_B , and W_B combination, the skeletal muscles are minimally stimulated. The average current ($i_B \times$ duty cycle) is preferably less than 20 mA, and more preferably less than 10 mA.

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The subthreshold stimulus from the background pulse trains 90 tends to reduce the pacing pulse trains' stimulation of the skeletal muscles, possibly through accommodation of those muscles.

5 That is, by adding the background pulse trains, the discomfort from stimulation of skeletal muscle during cardiac pacing is less than it would be without the background pulses (when the pacing stimuli are at threshold).

10 Given the physiological differences between cardiac muscle and skeletal muscle, the background pulse characteristics are accordingly selected to enhance accommodation of the skeletal muscles while discouraging accommodation of the cardiac muscle.

15 Preferably, the background pulse characteristics are selected to induce a level of skeletal muscle accommodation which increases the muscle stimulation threshold above the largest pacing pulse train stimuli amplitude. The background pulse trains 90,

20 together with the pacing pulse trains 80, thereby tend to produce reduced stimulation of the skeletal muscles while simultaneously achieving effective stimulation of the heart.

The background pulse trains and pacing pulse trains also decrease the cutaneous nerve stimulation associated with transcutaneous cardiac pacing.

25 Because the skeletal muscles and cutaneous nerves have similar chronaxies (Fig. 4), the cutaneous nerves, like skeletal muscles, tend to be stimulated less by the pulses in the pacing pulse trains than they would if the pacing pulse were a single continuous pulse. Furthermore, the background pulse train characteristics selected to produce accommodation of skeletal muscles accordingly

30 produce accommodation of cutaneous nerves.

35

Referring again to Fig. 1, the signal generator's waveform-shaping circuitry 60 modifies

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the stream of pulses generated by the oscillator circuitry 40 to create and distinguish the pacing and background pulse trains in the pacing stimuli 65. This modification may require amplitude or polarity adjustment for the particular electrodes used with the signal generator, as discussed below. The timing and control circuitry 20 provides further fine adjustment of the pacing pulse train characteristics, for example, pulse shape. Both the waveform-shaping circuitry 60 and the timing and control circuitry 20 may be programmed to include or omit any or more of the electrical signal characteristics discussed above.

In view of the reduced skeletal muscle and cutaneous nerve stimulation that is achieved by the pacing and background stimuli, the contribution of the electrode configuration to stimulation reduction may be less important. Thus, conventional noninvasive pacing electrodes with nonmetallic skin-contacting members, such as those disclosed in U.S. Patent No. 4,349,030, or as sold by R-2, of Morton Grove, Illinois, Physio-Control Corporation, of Redmond, Washington, or ZMI Corporation, of Woburn, Massachusetts, are suitable for delivering the pacing pulse trains. Alternatively, electrodes having metallic skin-contacting members may be adapted to deliver the pacing stimuli.

Another suitable electrode configuration is shown in Fig. 5. The anterior electrode 72 and posterior electrode 70 are adapted to deliver the pacing stimuli 65 from the signal generator 10 to a patient. A variety of electrode structures may be adequately used to achieve this function. Preferably, the electrodes are configured so that pacing pulse trains are delivered through the skin and skeletal muscles to the heart, whereas background pulse trains, if existent, are delivered

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only to the skin and skeletal muscles, and not to the heart. This electrode configuration ensures that cardiac fibrillation will not be induced by the background pulse trains.

5 As shown in Fig. 5, in this configuration, the electrodes 70, 72 are divided into central, isolated regions 70a, 72a, and surrounding annular regions 70b, 72b. Each of the central regions is separated from its corresponding annular region by a distance
10 which is adequate to provide electrical isolation between the two regions, e.g., at least one-quarter inch. The lateral region within this separating distance may be filled with an adhesive to act as an insulating material between the inner and outer
15 electrode regions.

 During delivery of a pacing pulse train, or the "pacing period," the stimuli are passed through the patient's thorax from the posterior electrode's central region 70a to the anterior electrode's
20 central region 72a. During delivery of a background pulse train, or the "background period," the pacing stimuli never pass through the patient, but instead pass between the central and annular regions of each electrode, as shown in Fig. 5. The polarity of, or
25 direction in which, the background stimuli are applied to the patient through the electrodes may be suitably altered without decreasing the effectiveness of the pacing stimuli for pacing the patient's heart. If no background pulse trains are
30 present, the entire stimuli may pass through the patient's thorax from one central region 70a (anode) to the other central region 72a (cathode).

 Other embodiments of the invention are within the claims. For example, the background pulses
35 could be used with conventional continuous pacing pulses, and could be applied continuously (even during the pacing stimuli). The background pulses

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could be monophasic. Individual background pulses could have non-rectangular shapes, e.g., triangular, exponential, or rounded. The amplitude, duration, and duty cycle of the background pulses could vary over time. Gaps could be present in the train of background pulses. Other variations in the embodiments are disclosed in my copending application Method and Apparatus for Transcutaneous Electrical Cardiac Pacing filed on even date herewith (hereby incorporated by reference).

What is claimed is:

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1 1. Apparatus for transcutaneously pacing the
2 heart at a pacing rate, the apparatus comprising
3 stimuli generating circuitry for generating
4 electrical stimuli, and
5 electrodes connected to the output of the
6 stimuli generating circuitry for delivering the
7 electrical stimuli to the patient,
8 wherein said stimuli generated and delivered to
9 the patient include
10 pacing stimuli occurring generally at the
11 pacing rate, and having a shape and amplitude
12 capable of causing contractions of the cardiac
13 muscle, and
14 background stimuli occurring at times
15 other than said pacing stimuli, and having a shape
16 and amplitude incapable of causing contractions of
17 the cardiac muscle.

1 2. The apparatus of claim 1 wherein said
2 background stimuli occur only at times other than
3 said pacing stimuli.

1 3. The apparatus of claim 1 wherein each said
2 background stimulus comprises a series of background
3 pulses.

1 4. The apparatus of claim 3 wherein each said
2 pacing stimulus comprises a series of pacing pulses.

1 5. The apparatus of claim 4 wherein the
2 average amplitude of said background pulses is less
3 than the average amplitude of said pacing stimuli.

1 6. The apparatus of claim 5 wherein the duty
2 cycle of said background pulses is less than 80%.

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1 7. The apparatus of claim 6 wherein said duty
2 cycle is less than 50%.

1 8. The apparatus of claim 5 wherein said
2 series of background pulses has an average current
3 amplitude of less than 20 mA.

1 9. The apparatus of claim 8 wherein said
2 series of background pulses has an average current
3 amplitude of less than 10 mA.

1 10. The apparatus of claim 6 wherein each
2 series of pulses is capable, as a group, of causing
3 a contraction of the heart, but each individual
4 pulse is incapable, by itself, of causing such a
5 contraction.

1 11. The apparatus of claim 10 wherein the
2 duration of the individual pacing pulses averages
3 less than 0.5 msec.

1 12. The apparatus of claim 11 wherein the duty
2 cycle of said individual pulses is at least 20%.

1 13. The apparatus of claim 11 wherein the
2 amplitudes of said series of individual pacing
3 pulses rise from a first amplitude to a second
4 amplitude.

1 14. Electrodes for transcutaneous pacing, said
2 electrodes comprising
3 a first electrical terminal for making a
4 connection to an external source of electrical
5 current,
6 a second electrical terminal for making a
7 connection to an external source of electrical
8 current,

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9 a first skin-contacting region electrically
10 connected to said first terminal of the electrode,
11 and
12 a second skin-contacting region electrically
13 insulated from said first region and spaced
14 laterally from said first region and electrically
15 connected to said second terminal of the electrode.

1 15. The electrodes of claim 14 wherein said
2 first region laterally surrounds said second region.

1 16. The electrode of claim 15 wherein said
2 second region is generally circular and said first
3 region is generally annular.

1 17. A method of transcutaneously pacing the
2 heart at a pacing rate, the method comprising the
3 steps of:
4 generating electrical stimuli;
5 delivering the stimuli to a patient through
6 electrodes applied to the patient's chest;
7 wherein the stimuli generated and delivered to
8 the patient include
9 pacing stimuli occurring generally at the
10 pacing rate, and having a shape and amplitude
11 capable of causing contractions of the cardiac
12 muscle, and
13 background stimuli occurring at times
14 other than said pacing stimuli, and having a shape
15 and amplitude incapable of causing contractions of
16 the cardiac muscle.

1 18. The method of claim 17 wherein said
2 background stimuli occur only at times other than
3 said pacing stimuli.

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1 19. The method of claim 17 wherein each said
2 background stimulus comprises a series of background
3 pulses.

1 20. The method of claim 19 wherein each said
2 pacing stimulus comprises a series of pacing pulses.

1 21. The method of claim 20 wherein the average
2 amplitude of said background pulses is less than the
3 average amplitude of said pacing stimuli.

1 22. The method of claim 21 wherein the duty
2 cycle of said background pulses is less than 80%.

1 23. The method of claim 21 wherein said duty
2 cycle is less than 50%.

1 24. The method of claim 21 wherein said series
2 of background pulses has an average current
3 amplitude of less than 20 mA.

1 25. The method of claim 24 wherein said series
2 of background pulses has an average current
3 amplitude of less than 10 mA.

1 26. The method of claim 22 wherein each series
2 of pulses is capable, as a group, of causing a
3 contraction of the heart, but each individual pulse
4 is incapable, by itself, of causing such a
5 contraction.

1 27. The method of claim 26 wherein the
2 duration of the individual pacing pulses averages
3 less than 0.5 msec.

1 28. The method of claim 27 wherein the duty
2 cycle of said individual pulses is at least 20%.

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1 29. The method of claim 27 wherein the
2 amplitudes of said series of individual pacing
3 pulses rise from a first amplitude to a second
4 amplitude.

1 30. The method of claim 17 wherein the pacing
2 and background stimuli are delivered through
3 electrodes whose configurations are different during
4 the pacing and background stimulation intervals so
5 that the background stimuli are, for the most part,
6 not delivered through the chest but the pacing
7 stimuli are delivered through the chest.

1 31. The method of claim 30 wherein one
2 electrode is applied to either side of the chest,
3 and the electrodes each comprise
4 a first electrical terminal for making a
5 connection to an external source of electrical
6 current,
7 a second electrical terminal for making a
8 connection to an external source of electrical
9 current,
10 a first skin-contacting region electrically
11 connected to said first terminal of the electrode,
12 and
13 a second skin-contacting region electrically
14 insulated from said first region and spaced
15 laterally from said first region and electrically
16 connected to said second terminal of the electrode,
17 and wherein
18 the background stimuli are passed between the
19 first and second skin-contacting regions of the same
20 electrode, and the pacing stimuli are passed between
21 from one electrode to the other electrode.

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- 1 32. The electrodes of claim 31 wherein said
- 2 first region laterally surrounds said second region.

AMENDED CLAIMS

[received by the International Bureau on 15 November 1991 (15.11.91);
original claims 1-32 replaced by amended claims 1-14
(2 pages)]

1 1. Apparatus for transcutaneously pacing the
2 heart at a pacing rate, the apparatus comprising
3 stimuli generating circuitry for generating electrical
4 stimuli, and
5 electrodes connected to the output of the stimuli
6 generating circuitry for delivering the electrical
7 stimuli to the patient,
8 wherein the electrical stimuli include pacing stimuli
9 delivered at the pacing rate, each pacing stimulus
10 comprising a train of individual pulses.

1 2. The apparatus of claim 1 wherein the duration
2 of the train of pulses has a duration long enough to
3 stimulate a contraction of the heart, but the duration of
4 the individual pulses is less than what is required to
5 stimulate such a contraction.

1 3. The apparatus of claim 1 wherein the duration
2 of said train is at least 5 msec.

1 4. The apparatus of claim 1 wherein the duration
2 of the individual pulses is less than 0.5 msec.

1 5. The apparatus of claim 4 wherein the duration
2 of the individual pulses is less than 100 microseconds.

1 7. The apparatus of claims 4, 5, or 6, wherein
2 the duty cycle of the individual pulses is less than 20%.

1 8. The apparatus of claim 7 wherein the
2 amplitudes of the individual pacing pulses rise from a
3 first amplitude to a second amplitude during the pulse
4 train.

1 9. The apparatus of claim 8 wherein the first
2 amplitude is less than the threshold for stimulation of
3 skeletal muscle.

1 10. The apparatus of claim 9 wherein the second
2 amplitude is reached in not less than 2 pulses.

1 11. The apparatus of claim 1 wherein the train of
2 individual pulses is such that, at the threshold for
3 cardiac stimulation there is less skeletal muscle
4 stimulation than would result using a continuous pulse
5 having the same duration as the train of pulses.

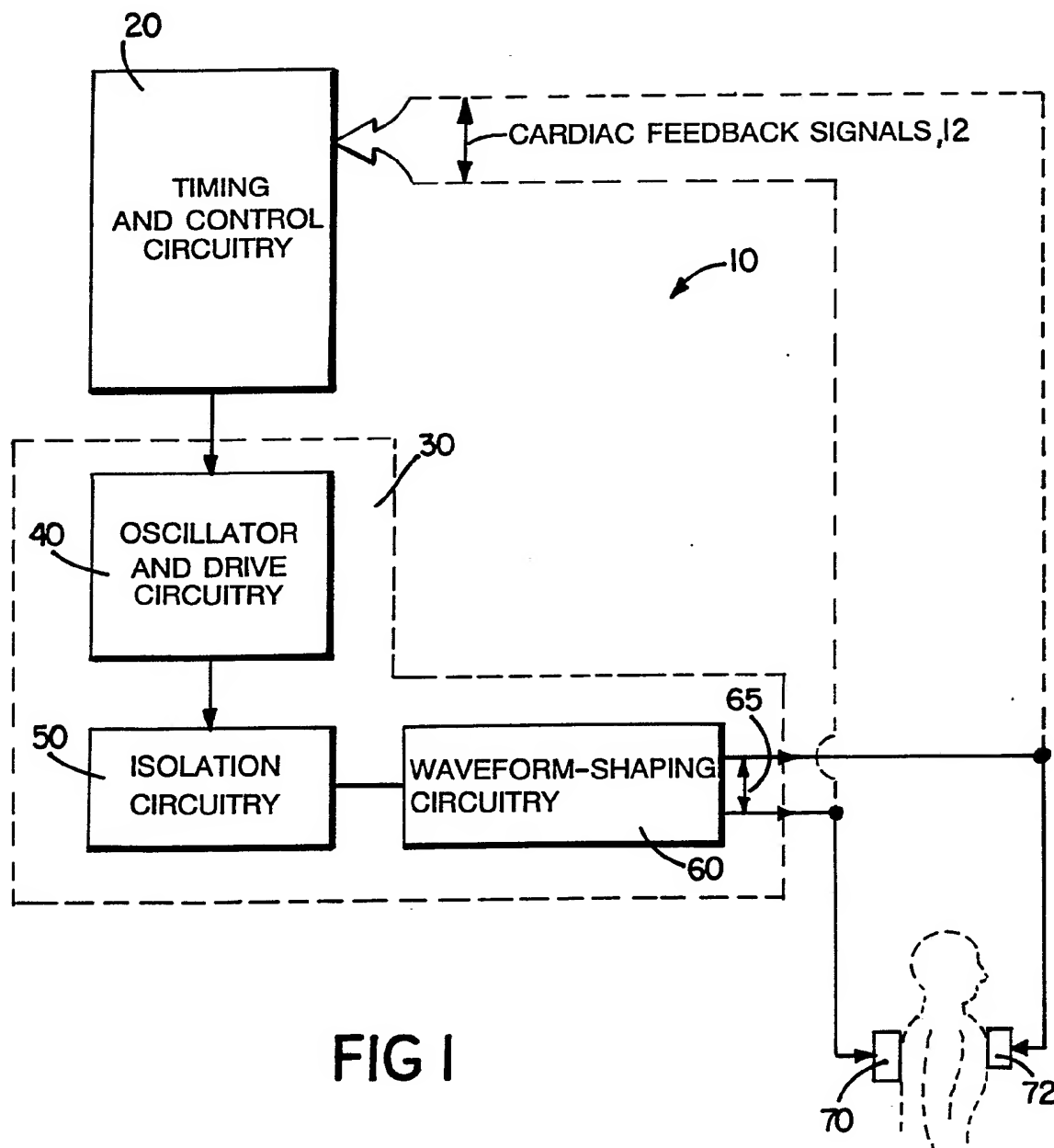
1 12. The apparatus of claim 1 wherein the train of
2 individual pulses is such that, at the threshold for
3 cardiac stimulation there is less discomfort to the
4 patient than would result using a continuous pulse having
5 the same duration as the train of pulses.

1 13. Apparatus for transcutaneously pacing the
2 heart at a pacing rate, the apparatus comprising
3 stimuli generating circuitry for generating electrical
4 stimuli, and

5 electrodes connected to the output of the stimuli
6 generating circuitry for delivering the electrical
7 stimuli to the patient,

8 wherein the electrical stimuli include pacing stimuli
9 delivered at the pacing rate, each pacing stimulus
10 comprising a plurality of pulses, with at least the
11 initial pulse in each stimulus having an amplitude less
12 than the threshold for causing contractions of skeletal
13 muscle and cardiac muscle, and subsequent pulses have
14 amplitudes greater than the threshold.

1 14. The apparatus of claim 13 wherein each
2 succeeding initial pulse has a generally greater
3 amplitude than the preceding pulses.



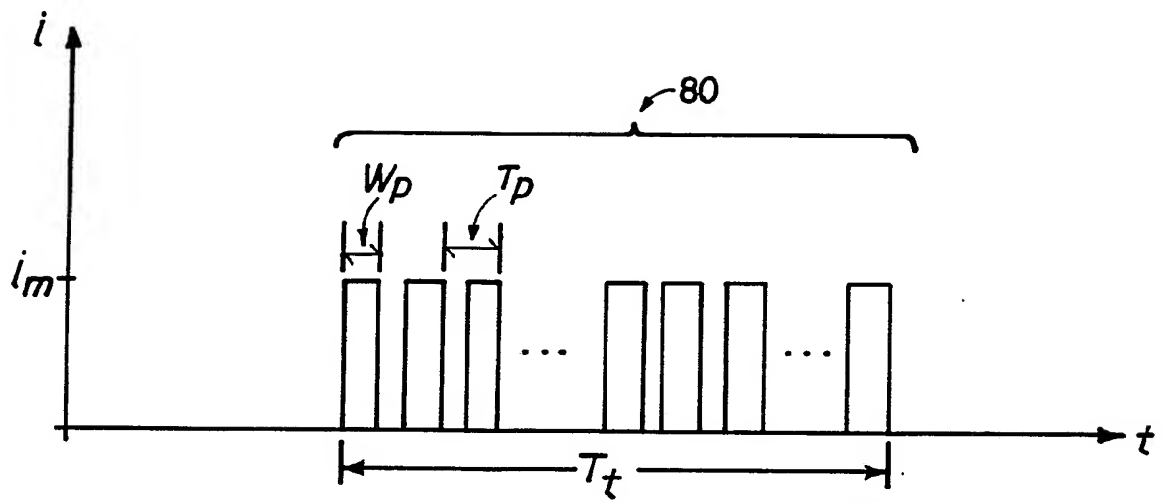


FIG. 2A

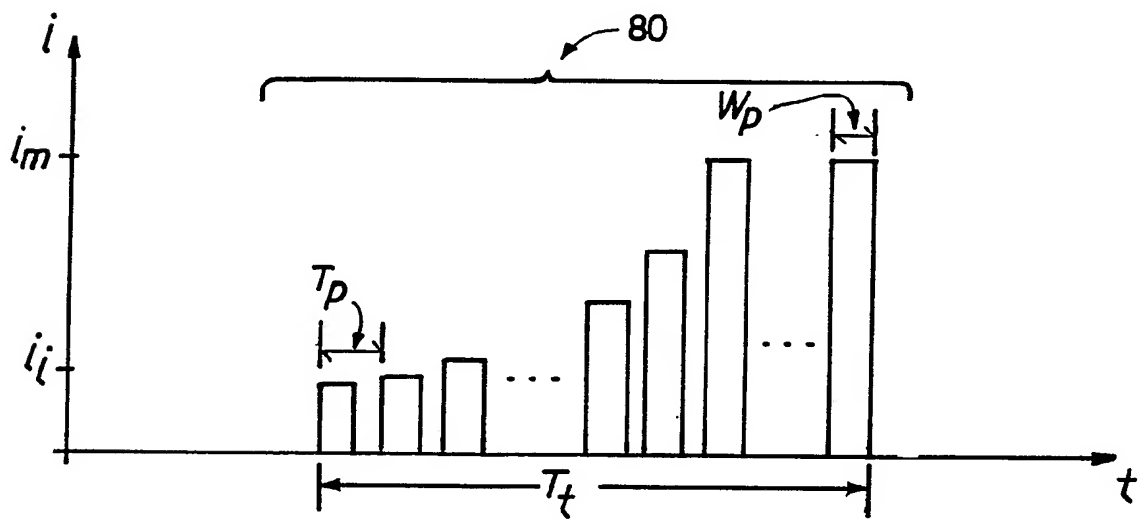


FIG. 2B

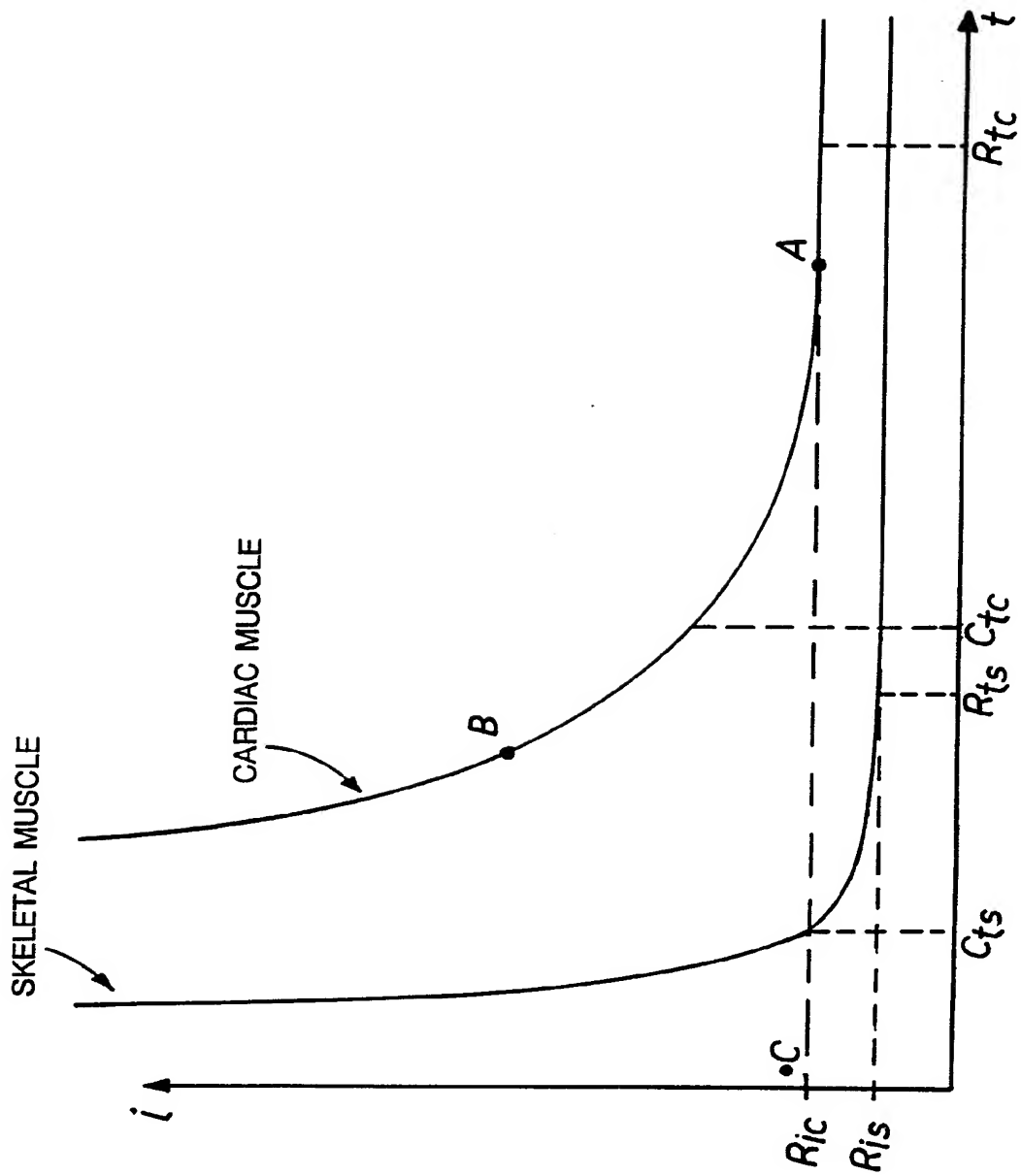


FIG. 3

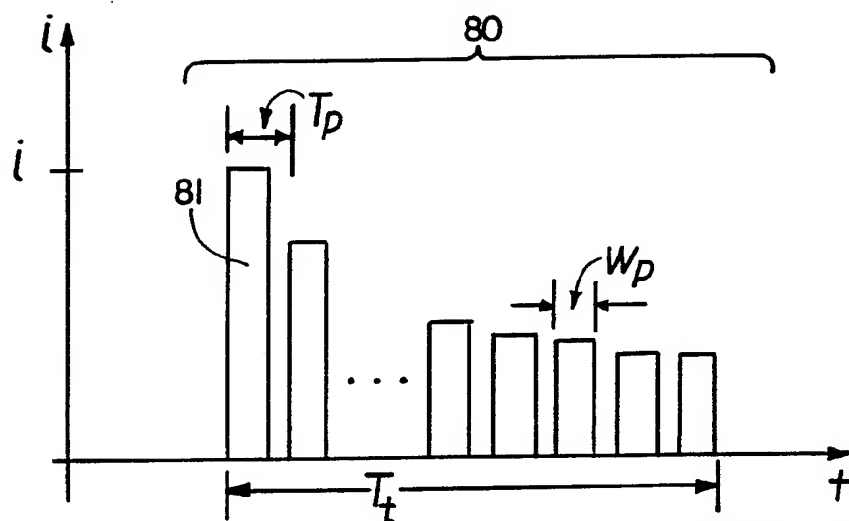


FIG. 4A

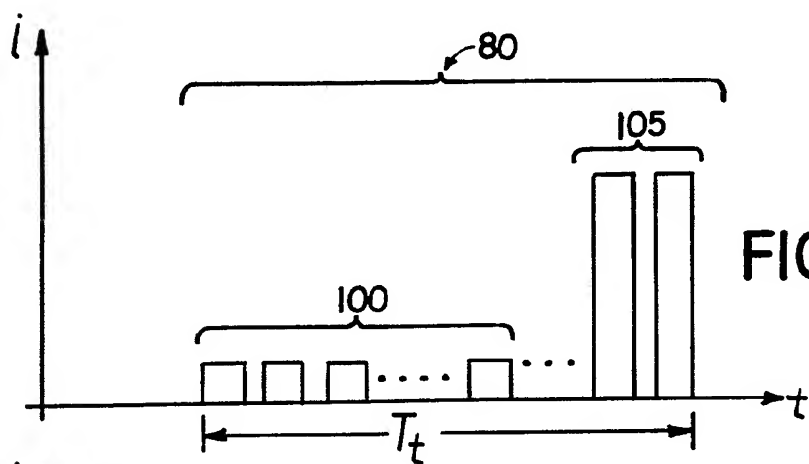


FIG. 4B

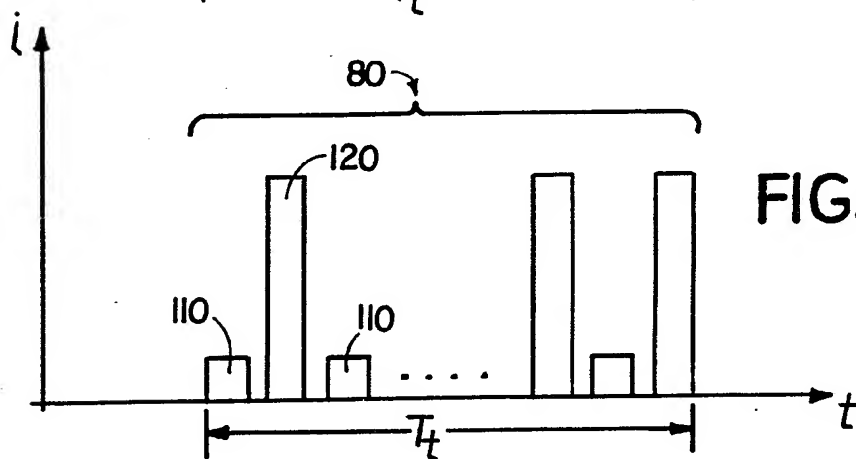


FIG. 4C

INTERNATIONAL SEARCH REPORT

International Application No. **PCT/US91/04185**

| I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC IPC(5): A61N 1/362 US CL.: 128/419.0PG | | | | | | | | | | | |
|---|---|-------------------------------------|---|---|-------------------------------------|----|--|-------------|---|--|----|
| II. FIELDS SEARCHED <div style="text-align: right; font-size: small;">Minimum Documentation Searched ⁷</div> <table style="width: 100%; border: none;"> <tr> <td style="width: 25%; border: none; vertical-align: top;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 20%; padding: 2px;">Classification System ⁴</th> <th style="padding: 2px;">Classification Symbols</th> </tr> <tr> <td style="text-align: center; padding: 5px;">US</td> <td style="padding: 5px;">128/419.0PG, 419.00D, 421</td> </tr> </table> </td> <td style="border: none;"></td> </tr> </table> <div style="text-align: center; font-size: x-small; margin-top: 5px;"> Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸ </div> | | | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 20%; padding: 2px;">Classification System ⁴</th> <th style="padding: 2px;">Classification Symbols</th> </tr> <tr> <td style="text-align: center; padding: 5px;">US</td> <td style="padding: 5px;">128/419.0PG, 419.00D, 421</td> </tr> </table> | Classification System ⁴ | Classification Symbols | US | 128/419.0PG, 419.00D, 421 | | | | |
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| III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 10%; padding: 2px;">Category ⁹</th> <th style="width: 70%; padding: 2px;">Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²</th> <th style="width: 20%; padding: 2px;">Relevant to Claim No. ¹³</th> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">US, A, 4,787,389 (TARJAN) 29 November 1986 See entire document.</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1-13, 17-32</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">US, A, 4,580,570 (SARRELL) 08 April 1986 See entire document.</td> <td style="text-align: center; vertical-align: top; padding: 5px;">14</td> </tr> </table> | | | Category ⁹ | Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹² | Relevant to Claim No. ¹³ | A | US, A, 4,787,389 (TARJAN) 29 November 1986 See entire document. | 1-13, 17-32 | X | US, A, 4,580,570 (SARRELL) 08 April 1986 See entire document. | 14 |
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| <div style="display: flex; justify-content: space-between; font-size: x-small;"> <div style="width: 45%;"> <p>[*] Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div> | | | | | | | | | | | |
| IV. CERTIFICATION <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;"> Date of the Actual Completion of the International Search </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;"> 19 AUGUST 1991 </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;"> International Searching Authority </div> <div style="border: 1px solid black; padding: 2px;"> ISA/US </div> </td> <td style="width: 50%; border: none; vertical-align: top;"> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;"> Date of Mailing of this International Search Report </div> <div style="text-align: center; font-size: large; font-weight: bold; margin-bottom: 5px;"> 13 SEP 1991 </div> <div style="border: 1px solid black; padding: 2px;"> Signature of Authorized Officer <i>Nguyen</i> NGUYEN NGOC HO INTERNATIONAL DIVISION <i>for</i> SCOTT GEIZOW </div> </td> </tr> </table> | | | <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;"> Date of the Actual Completion of the International Search </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;"> 19 AUGUST 1991 </div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;"> International Searching Authority </div> <div style="border: 1px solid black; padding: 2px;"> ISA/US </div> | <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;"> Date of Mailing of this International Search Report </div> <div style="text-align: center; font-size: large; font-weight: bold; margin-bottom: 5px;"> 13 SEP 1991 </div> <div style="border: 1px solid black; padding: 2px;"> Signature of Authorized Officer <i>Nguyen</i> NGUYEN NGOC HO INTERNATIONAL DIVISION <i>for</i> SCOTT GEIZOW </div> | | | | | | | |
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